REMARKS/ARGUMENTS

Claims 5-21 are pending in this application with Claims 5, 6, 9, 10, and 12 being in independent form.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 5-11 and 19-21

Claims 5-11 and 19-21 were rejected under 35 U.S.C. § 112, first paragraph, because it is the Examiner's position that the specification, while being enabling for a topical nail formulation *with* a specific applicating agent, does not provide enablement for the broad applicating agent limitation found in the independent claims. The Examiner, however, has failed to carry her burden of establishing a reasonable basis to question the enablement of the applicating agent. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). *See also* MPEP § 2164.04. The Examiner's cursory analysis of the *Wands* factors insufficiently explains how she concluded one of ordinary skill in the art could not have made or used the invention without undue experimentation. *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). *See also* MPEP § 2164.01 (a). The eight *Wands* factors, as applied to this application, are discussed in detail below.

First, the Applicant agrees with the Examiner that the nature of the invention is a topical nail formulation and the method of making the same. The nature of the invention is simple and is not complicated, for example, by highly technical protein assays, screening procedures, or cloning DNA fragments. Instead, the topical nail formulation is made by simply mixing together common chemical compounds, one of which is an applicating agent. The applicating agent is defined in the specification [0012] as an ointment, a lotion, a nail polish, or a combination

thereof. The specification [0012] provides further enablement for the applicating agent by specifically identifying oxyquinoline, petrolatum, lanolin, glycerine, or a combination thereof as appropriate ointments. The simple nature of the invention weighs in favor of a minimal standard for enablement and is relevant in determining two other *Wands* factors: the state of the art and the level of skill in the art.

Second, the Examiner recognizes that the state of the cosmetic/pharmaceutical art is highly developed. This factor also weighs in favor of a minimal standard for providing an enabling disclosure. The prior art, previously cited by the Examiner, is evidence that the cosmetic/pharmaceutical art is particularly developed in the field of pharmaceutical formulations. *See* Topical Treatment of Hyperproliferative Skin Diseases, U.S. Patent No. 4,696,946 (filed Aug. 30, 1985) (issued Sep. 29, 1987) ("the '946 Patent"). The '946 Patent teaches a pharmaceutical formulation, one component of which is a "pharmaceutically acceptable topical carrier." (col. 7, lines 57-60). The '946 Patent further teaches using an ointment, a lotion, a cream, a spray, a powder, or an aerosol as the topical carrier. (col. 8, lines 15-19). Additionally, the '946 Patent teaches recipes for making an ointment, a cream, a gel, a lotion, and an aerosol. (col. 8, line 54 – col. 10, line 36). A specification need not disclose, and preferably omits, the subject matter which is well-known to those skilled in the art and already available to the public. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991). *See also* MPEP § 2164.05 (a). The Applicant's specification provides enablement for the applicating agent without disclosing any recipes because they are already well-known to those skilled in the art and are available to the public through the '946 Patent and other readily available sources. For example, a quick internet search for "ointment base" using Google yields over one million

results including websites with ointment, lotion, cream, etc. composition details. The top 20 Google hits and two example website printouts are attached as Exhibit A (8 pages).

Third, the Examiner admits that the level of knowledge possessed by a person of ordinary skill in the art is high. The Examiner has identified a person having a Medical Doctorate (M.D.) degree as a person of ordinary skill in the cosmetic/pharmaceutical art. A person with the extensive education that an M.D. degree requires, would have knowledge of an appropriate ointment, lotion, nail polish, or combination thereof that would be safe and function well as an applicating agent for nails. Furthermore, a person having an M.D. degree would be familiar with the specific ointment examples disclosed in the specification [0012]. The specification [0012] also suggests using a clear nail polish for an aesthetically neutral applicating agent, another factor one of ordinary skill in the art would consider. The amount of disclosure in the Applicant's specification is certainly sufficient to enable a person with an M.D. degree to select an appropriate applicating agent for use in the topical nail formulation. The amount of disclosure required for a medical doctor to practice the invention is much less than would be required for a Bachelor's degree scientist.

Fourth, the Applicant agrees with the Examiner that the art is predictable. This is still another factor weighing in favor of a minimal standard of disclosure for enablement. An art is predictable when an ordinarily skilled artisan can extrapolate known results to the claimed invention or can anticipate the effect of a change within the subject matter. *See* MPEP § 2164.03. As previously stated, the use of different applicating agents in combination with a chemical to topically treat diseases is well known in the cosmetic/pharmaceutical art. *See* The '946 Patent. A person with an M.D. degree could predict what applicating agent would be safe and effective for use in a topical nail formulation for treating a fungus infection. As a result of

the highly developed state of the art, a person with an M.D. degree could also predict how changing the type of applicating agent would affect the effectiveness and safety of the topical nail formulation. For example, such a person would know what applicating agent would be chemically compatible with the other compounds in the topical nail formulation. The specification provides enablement for the applicating agent because one of ordinary skill in the art could predict what effect changing the type of applicating agent in the resulting topical nail formulation would occur.

Fifth, the Examiner states that the independent claims are broad with respect to the use of an applicating agent. The Examiner's analysis is insufficient because she does not explain why the breadth of the claims is problematic or point out what subset of the subject matter she considers to be enabled. *See* MPEP § 2164.08. The Applicant submits that the term applicating agent, although broad, is within the scope of the enabling disclosure. By disclosing specific types of applicating agents, and further disclosing specific compounds, the specification [0012] provides enablement for the term. It is not necessary for the independent claims to be limited any further because the invention is not complex, the prior art is highly developed and predictable, and the level of ordinary skill in the art is very high. With the many examples of types of applicating agents set forth in the specification along with specific examples, there is no basis for the Examiner's position that the disclosure is not enabling for the broad term applicating agent.

Sixth, as the Examiner points out, the specification discloses a working example. In general, a specification need not contain any examples, and "the presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure." MPEP § 2164.02 ("Compliance with the enablement requirement of 35 U.S.C. 112,

first paragraph, does not turn on whether an example is disclosed."). The working example (Example 1) disclosed in the specification [0024] uses an ointment as the applicating agent in the topical nail formulation. Although the specific ointment compound used in the example is not mentioned, the specification [0012] previously disclosed that an ointment could be oxyquinoline, petrolatum, lanolin, glycerine, or a combination thereof. Additionally, the Examiner has not advanced any reason why a person of ordinary skill in the art (a medical doctor) could not instead select a lotion, a nail polish, or a combination thereof as the applicating agent without requiring undue experimentation to make and use the topical nail formulation. *See* MPEP § 2164.02 ("Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person of ordinary skill in the art could not use the genus as a whole without undue experimentation."). The highly developed state of the art, the predictability of the art, the fact that all of the disclosed categories of applicating agents are commonly available, and the advanced level of skill possessed by an ordinary artisan support the interchangeability of different applicating agents in an effective topical nail formulation without undue experimentation. The working example is further evidence that the specification provides enablement for the applicating agent.

The Applicant disagrees with the Examiner's findings with respect to the two remaining *Wands* factors. First, the Examiner's statement that the specification does not provide any guidance and/or direction as to what ointment, what nail polish, or what lotion can be added to obtain a topical nail formulation is incorrect. The specification [0012] directs and guides one of ordinary skill in the art to use oxyquinoline, petrolatum, lanolin, glycerine, or a combination thereof as an ointment applicating agent. The specification [0012] also suggests that when using a nail polish as the applicating agent, the nail polish could be clear. Further guidance and/or

direction is not necessary because the Examiner and the Applicant agree that the state of the art is highly developed and the art is predictable. *In re Fisher*, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970) (holding the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the art as well as the predictability of the art). *See also* MPEP § 2164.03. The details in the specification provide enablement for the applicating agent because a person with an M.D. degree and knowledge of the prior art would not need any more guidance and/or direction to make and use the topical nail formulation.

Second, the Examiner, in attempting to analyze the quantity of experimentation needed to make or use the invention, simply concluded that undue experimentation would be required. These types of conclusory allegations are impermissible, and insufficient to establish a proper rejection for lack of enablement. *See* MPEP § 2164.04. The Examiner must specifically identify why one skilled in the art could not supply the missing information without requiring undue experimentation. Even if a considerable amount of experimentation is necessary, as long as it is routine then it is not undue. *In re Angstadt*, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). *See also* MPEP § 2164.01 ("The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue."); MPEP § 2164.06. A person having an M.D. degree (one of ordinary skill in the cosmetic/pharmaceutical art) could routinely experiment with the applicating agents disclosed in the specification [0012] for purposes of adjusting ease of application or aesthetic appearance once applied. However, little if any experimentation is required to make and use an effective antifungal topical nail formulation. Example 1 in the specification [0024], is evidence that use of an ointment as an applicating agent results in an effective nail formulation. The specification provides enablement for an applicating agent because no further experimentation is necessary to make and use a topical nail formulation

if an ointment is selected, and only routine experimentation might be required if another type of applicating agent is selected.

Based on the foregoing, the Applicant submits that Claims 5-11 and 19-21 are supported by an enabling disclosure and respectfully requests removal of the rejection of such claims under 35 U.S.C. § 112, first paragraph.

Claims 12-18

Claims 12-18 were rejected under 35 U.S.C. § 112, first paragraph, because it is the Examiner's position that the specification, while being enabling for a topical nail formulation *with* a specific applicating agent, does not provide enablement for a method of treating a nail of a patient where the broad term applicating agent is used. The Examiner's findings for each of the *Wands* factors for this rejection closely parallel the findings discussed above. For the same reasons previously stated, the Applicant submits, and the Examiner has agreed, that the nature of the invention is simple, the state of the prior art is highly developed, a person having an M.D. degree is a person possessing the ordinary level of skill in the art, the art is predictable, a working example is disclosed, and the applicating agent limitation, as used in Independent Claim 12, is broad.

The Applicant disagrees with the Examiner with respect to the two remaining *Wands* factors. First, the Examiner states that the direction and guidance provided by the inventor is unclear and insufficient because the specification fails to point out what constitutes an ointment. This is incorrect. The specification [0012] teaches that oxyquinoline, petrolatum, lanolin, glycerine, or a combination thereof each constitutes an ointment. Furthermore, Claims 12-18 are directed to a method of treating a nail of a patient by providing a topical nail formulation. In the working example, the specification [0024] guides one of ordinary skill in the art to choose an

ointment as the applicating agent in the topical nail formulation. The specification [0020] then instructs how and when to apply the formulation to treat the patient. These details provide sufficient direction and/or guidance because the state of the art is highly developed and the level of ordinary skill in the art is high (M.D. degree level). *Fisher*, 166 U.S.P.Q. at 24 (holding the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the art as well as the predictability of the art). *See also* MPEP § 2164.03. The specification provides enablement for a method of treating the nail of a patient because the direction and guidance contained therein is sufficient for a person with an M.D. degree level of skill to understand what constitutes an ointment as an applicating agent.

Second, the Examiner argues that one of ordinary skill in the art would be required to perform undue experimentation to select a specific applicating agent for a nail formulation used to treat a nail fungal infection, although the Examiner does not provide any reason why experimentation is necessary or undue. Considering the factors previously discussed, most of which weigh in favor of a minimal standard of disclosure for enablement, it is submitted that the objective criteria all point to the disclosure being enabling. As previously identified, the specification [0012] discloses using an ointment as the applicating agent and further discloses several readily available ointment compounds that would be appropriate. Example 1 is evidence of one method of using a nail formulation with an ointment applicating agent to treat a nail fungal infection. No experimentation is required to practice the method disclosed in Example 1. *Fisher*, 166 U.S.P.Q. at 24. *See also* MPEP § 2164.01 (b) ("As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of U.S.C. 112 is satisfied."). Any further experimentation by a medical doctor seeking to practice the invention,

such as determining ease of application or aesthetic appearance, would be routine and require minimal effort.

Based on the foregoing, the Applicant submits that Claims 12-18 are supported by an enabling disclosure and respectfully requests removal of the rejection of such claims under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 5-21

Claims 5-21 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because it is the Examiner's position that the applicating agent limitation is unclear, specifically if the applicating agent, as an ointment, a lotion, a nail polish, or a combination thereof, is separately added to the formulation or if the formulation itself is in the form of an ointment, a lotion, a nail polish, or a combination thereof.

The term applicating agent as disclosed in the specification is clear. The Applicant uses the terms ointment, lotion, nail polish, and combinations thereof to define applicating agent in the specification [0012] and never uses those terms to refer to the topical nail formulation. The specification [0007] [0009] [0016] 0017] [0018] [0024] discloses that the applicating agent is one component of the topical nail formulation. The specification [0009] specifically states, for example, that the "formulation includes a mixture of calcium hydroxide, sodium hydroxide, an antifungal agent, and an applicating agent." Additionally, a method of making the formulation [0018] includes mixing the applicating agent with the other components. The specific order of incorporating each component into the formulation makes clear that the applicating agent is added to the other components as part of the formulation. Although the type of applicating agent

used may affect the consistency of the end product, the formulation itself is never defined as an ointment, a lotion, a nail polish, or a combination thereof.

Based on the foregoing, the Applicant submits that Claims 5-21 are definite and respectfully requests removal of the rejection of such claims under 35 U.S.C. § 112, second paragraph.

In view of the foregoing remarks, it is respectfully submitted that the claims are in condition for allowance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By: _____

J. David Wharton, Reg. No. 25,717
Susan Wharton Bell, Reg. No. 41,524
STINSON MORRISON HECKER LLP
1201 Walnut, Suite 2900
Kansas City, MO 64106-2150
Telephone: (816) 842-8600
Facsimile: (816) 691-3495

EXHIBIT A

Sign in

Google Web Images Groups News Froogle Maps more »

ointment base Search Advanced Search Preferences

Web

Results 1 - 10 of about 1,100,000 for ointment base. (0.28 seconds)

Ointment base - definition from Biology-Online.org
Definition and other additional information on **Ointment base** from Biology-Online.org dictionary.
www.biology-online.org/dictionary/**Ointment_base** - 12k - Cached - Similar pages

Formulation design of **ointment base** suitable for healing of ...
We intended to develop a desired **ointment base** suitable for treatment of bedsores including the prol...
www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11217096&dopt=Abstract - Similar pages

[Preparation of a gel-forming **ointment base** applicable to the ...
An **ointment base** for better treatment of bedsores was developed to improve the release rate of minoc...
www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=14978948&dopt=Abstract - Similar pages
[More results from www.ncbi.nlm.nih.gov]

Ointment Base Ingredients
Medco Lab, Inc. **Ointment Base** Ingredients ... Topical **Ointment**. **Ointment Base**™ (Water in oil **ointment**): Contains:. White Petrolatum, 80%. Lanolin Oil, 0.5% ...
www.medcolab.com/ingr**ointment**.htm - 7k - Cached - Similar pages

Ointment Base
If your pharmacist is unable to assist you, then you may order **Ointment Base**™ directly from Medco Lab, Inc. Fill out the online form below and one of our ...
www.medcolab.com/prod**ointment**.htm - 8k - Cached - Similar pages

PHA 5110, Ointments
roller mill; "levigating" the powder (reduction of particle size in suspending agent compatible with the **ointment base**). (2) Fusion: all or some components ...
www.cop.ufl.edu/safezone/prokai/pha5100/**Ointment**.htm - 8k - Cached - Similar pages

Procedure
Based on the physical properties of the various **ointment** bases studied, ... Which **ointment base** showed the most rapid release of salicylic acid? ...
pharmlabs.unc.edu/**ointment**s/text1.procedure.htm - 23k - Cached - Similar pages

Penreco | **Ointment** Bases Properties
Ointment Base No. 6, 122/133, 1.5Y, 195/230. To the best of our knowledge, the information contained herein is accurate, but is given without warranty or ...
www.penreco.com/products/petrolatums/**ointment**properties.asp - 26k - Cached - Similar pages

Base
104954, Anhydrous **Ointment Base**™, Lb, Oleaginous **ointment**, petrolatum and mineral oil. Hydrophilic (will pick up water). Not soluble in water, ...

EXHIBIT A

www.gallipot.com/ui/**Base**.aspx - 34k - Cached - Similar pages

Steroids - Topical Steroid Vehicles
For example, a topical steroid in an **ointment base** will be more potent than the same topical steroid in a cream or lotion **base**. This difference in potency ...
dermatology.about.com/cs/medications/a/steroidvehicle.htm - 28k - Cached - Similar pages

Try your search again on Google Book Search

Goooooooooogle ▶
Result Page: 1 2 3 4 5 6 7 8 9 10 **Next**

ointment base Search

Search within results | Language Tools | Search Tips | Dissatisfied? Help us improve

Google Home - Advertising Programs - Business Solutions - About Google

Sign in

Google

Web Images Groups News Froogle Maps more »

ointment base Search Advanced Search Preferences

Web

Results **11** - **20** of about **1,100,000** for **ointment base**. (**0.07** seconds)

Drugs and Treatments - **Ointment Base** Top - Patient Handout from WebMD

Information on **Ointment Base** Top - Patient Handout. Find the answers you need about over the counter and prescription medications, vitamins and supplements, ...
www.webmd.com/drugs/drug-13236-**Ointment**+**Base**+Top.aspx?drugid=13236&drugname=**Ointment**+**Base**+Top - 59k - Cached - Similar pages

Section 21CFR333.120

(1) Bacitracin- neomycin sulfate **ointment** containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable **ointment base**. ...
a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/aprqtr/21cfr333.120.htm - 7k - Cached - Similar pages

[PDF] Food and Drug Administration, HHS 333.120

File Format: PDF/Adobe Acrobat - View as HTML
chloride in a suitable **ointment base**. (d) Neomycin sulfate **ointment** con- ... oleaginous **ointment base**. (e) Neomycin sulfate cream con- ...
a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/pdf/21cfr333.120.pdf - Similar pages

Ointment base and method of use - Patent 5336692

High molecular weight petroleum fractions which have a low white oil content are admixed with a volatile siloxane, hexamethyldisiloxane, ...
www.freepatentsonline.com/5336692.html - 48k - Cached - Similar pages

Ointment Base

Applitto.net: **Ointment Base**. Applitto. ... **Ointment Base**. **Ointment Base** Top. OcuSoft Hand Soap - OcuSoft Hand Soap Top; Omedia Otic - BENZOCAINE ...
applitto.net/drugs/**Ointment**%20**Base**-5D78.html - 12k - Cached - Similar pages

First Aid Antibiotic

(b) Bacitracin zinc **ointment** containing, in each gram, 500 units of bacitracin zinc in a suitable **ointment base**. (c) Chlortetracycline hydrochloride ...
www.fda.gov/cder/otcmonographs/First_Aid_Antibiotic/first_aid_antibiotic(333B).htm - 16k - Cached - Similar pages

Xenaderm **Ointment** Clinical Studies

Abstract: Several controlled studies were performed in different subjects to evaluate the effects of a patented **ointment base** containing trypsin, ...
www.healthpoint.com/divisions/tm/prodXenadermclinstudies.cfm - 25k - Cached - Similar pages

RxMed: Pharmaceutical Information - LOCASALEN

Flumethasone pivalate, a topical corticoid of proven efficacy, is in solution in the **ointment base** rather than as suspended microcrystals and attains a ...

www.rxmed.com/.../b2.1.monographs/CPS-%20Monographs/CPS-%20(General%
20Monographs-%20L)/LOCASALEN.html - 22k - Cached - Similar pages

Hasco-Lek, Pharmaceutical Production Company
Hasco-Lek offers high quality substances for preparation of prescription medicines in the form of **ointment** and powder **base**. ...
www.hascolek.com/products_cat.php?mid=&
kid=11&HascoEng=895f1ba511cf513422ebdd3e7a322717 - 37k - Cached - Similar pages

YKKZAJ Contents, Vol.124, No.2 (2004) (English)
Preparation of a Gel-Forming **Ointment Base** Applicable to the Recovery Stage of Bedsore and Clinical Evaluation of a Treatment Method with Different **Ointment** ...
yakushi.pharm.or.jp/abst_2004/No2/no2.html - 14k - Cached - Similar pages

◀ Goooooooooogle ▶
Result Page: **Previous** 1 2 3 4 5 6 7 8 9 10 11 **Next**

ointment base Search

Search within results | Language Tools | Search Tips

Google Home - Advertising Programs - Business Solutions - About Google

Medco Lab, Inc.

Ointment Base Ingredients

Topical Ointment

Ointment Base™ (Water in oil ointment)
Contains:

White Petrolatum	80%
Lanolin Oil	0.5%
Isopropyl Palmitate	0.5%
Polyethylene Glycol 40 Stearate	3%
Sorbitan Sesquioleate	5%
Methylparaben	0.17%
Propylparaben	0.5%
Captan	0.5%
Sorbitol	0.6%
Propylene Glycol	0.6%

[Home] [Up]

This site designed and maintained by TWConsulting.

Send mail to webmaster with questions or comments about this web site.

Last modified: August 31, 2000

OINTMENTS, CREAMES, PASTES AND LOTIONS

Ointments are semisolid preparations intended for external uses. (**Skin and Percutaneous Absorption**)

- Medicated
- Non-medicated (ointment bases)
  - emollient or lubricant
  - vehicle for the preparation of medicated ointments

Ointment Bases

(1) Hydrocarbon bases

- Petrolatum (semisolid hydrocarbon, melting point 38-68 ^{o}C, yellow to light amber)
- White petrolatum (not water washable, occlusive)
- Yellow ointment (95 % petrolatum + 5 % purified wax)
- Mineral oil (liquid hydrocarbon from petrolatum)

(2) Absorption bases - Permit incorporation of aqueous solutions (form water/oil emulsions)

- Anhydrous lanolin (2 times of water/weight)
- Hydrophilic petrolatum (cholesterol, stearyl alcohol, white wax, white petrolatum
  - Aquaphor - refined hydrophilic petrolatum, takes up 3 time of water per weight

(3) Emulsion bases - water-in-oil type (already emulsions)

- Lanolin (from sheep wool): semisolid, fat-like substance, 25-30 % water
- Cold cream (cetyl ester wax, white wax, mineral oil, sodium borate, purified water + soap [fatty acid sodium salt] to emulsify)

(4) Emulsion bases - oil-in-water type (can be washed from skin or clothing with water)

- Hydrophilic ointment:
  - sodium laurylsulfate (emulsifying agent)
  - stearyl alcohol and white petrolatum (oily phase)
  - water and propylene glycol (aqueous phase)

(5) Water-soluble bases - contain only water soluble components (water-washable, "greaseless")

- Soften greatly with the addition of water. Aqueous solutions are not effectively incorporated, better for the incorporation of nonaqueous or solid substances.
  - Poly(ethylene glycol)/PEG ointment: 60/40 (w/w) PEG400/PEG3350
    - may contain 6-25 % water 5% stearyl alcohol, 60 % PEG 400, 35 % PEG 3350 (firm)

Selection of the Appropriate Base Based on

- Desired release rate
- Desirability for enhancement of percutaneous absorption
- Advisability of occlusion
- Short-term or long-term stability
- Influence of drug on consistency or other features of ointment base
- Patient factor - dry or weeping (oozing) skin

Preparation of Ointments

(1) Incorporation: mix together (mortar & pestle, spatula & slab)

- roller mill
- "levigating" the powder (reduction of particle size in suspending agent compatible with the ointment base)

(2) Fusion: all or some components of an ointment melted together and cooled with constant stirring until congealed, add non-melting substances as the ointment is being cooled and stirred

- in porcelain dish or beaker, industry: steel-jacketed kettles

Preservation of Ointments

- Microbial content (*Pseudomonas aeruginosa, Staphylococcus aureas*) determined and controlled
- Sterile preparations (some)
- Chemical antimicrobial preservatives: p-hydroxybenzoates, phenols, benzoic acid, sorbic acid, quaternary ammonium salts, organic mercury compounds, formaldehyde

Packaging and Storage (jars and tubes)

Creams

- Viscous liquid or semisolid emulsions of oil-in-water or water-in-oil type
- Easier to spread and easier to remove than ointments

Pastes

- Contain a larger percentage of solid material than ointments (thicker and stiffer)
- Will not soften and flow after application

Lotions

Liquid preparations containing finely powdered substances that are insoluble in the dispersion medium through the use of suspending agent, or have as the dispersed phase liquid substances that are immiscible with the vehicle and are usually dispersed by means of emulsifying agents. (Most commonly, the vehicles of lotions are aqueous).

Topical Solutions and Tinctures

- For external use only (mostly antiinfective agents)

- Aqueous vehicle (topical solution) or alcoholic vehicle (tincture)


Back to PHA 5110 Homepage